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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,815	03/29/2002	Preeti Lal	PF-0673 USN	2966

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,815	LAL ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 4, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-16,19 and 22-27* is/are pending in the application.

4a) Of the above claim(s) *1,2,8,9,12-16,19 and 22-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

Claims 7,17-18, 20-21 have been cancelled. **Claims 24-27** have been added. **Claims 1, 2, 4 and 10** have been amended. **Claims 1-6, 8-16, 19, 22-27** are pending in this application.

Response to applicant's election with traverse

Applicant's election with traverse of Invention of Group II, **Claims 3-6, 10 and 11** and the further election of SEQ ID NO: 10, in amendment, filed November 21, 2003 is acknowledged. The traversal is on the ground(s) that a unity of invention standard must be applied in all national stage applications.

The technical feature linking groups I-VI appears to be that they all relate to the expression of Leukocyte and blood-associated proteins.

However, Leavitt et al., US Patent 5,002,870 teach the expression of leukocyte and blood associated proteins (summary of the experimental results). Furthermore, Leavitt et al. teach isolated nucleic acid molecules encoding the mentioned protein, a cell transformed with the nucleic acid encoding the mentioned polypeptide, a method of making a protein by recombinant means, isolated antibody against the produced protein, a method of detecting a target polynucleotide in a sample and a method of screening a compound using a polypeptide (examples 1-8). Therefore, the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Therefore the requirement is still deemed proper and made Final. **Claims 1-2, 8-9, 12-16, 19, 22-27** are withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions.

Priority

The current application filed on March 29, 2002 is a 371 of PCT/US00/05133 filed on February 29, 2000, which in turn claims priority to provisional application, 60/122,080 filed on March 01, 1999.

Information Disclosure Statement

The IDS filed November 21, 2003 has been received and is signed and considered, a copy of the IDS is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 10** the term "complementary to " allows for a multiplicity of interpretations. For example, complementary in this case, could mean; a nucleotide sequence that has a high degree of homology to the original, a nucleotide sequence that comprises the original, or a nucleotide sequence that resembles the original in

regards to structural integrity. **Claim 11** is a dependent claim that does not further clarify the independent- **claim 10**.

Claim Rejection - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-6, 10 and 11 are rejected under U.S.C 101 because the claimed invention is not supported by either specific and substantial asserted utility or well established utility.

Claims 3-6, 10 and 11 are directed to isolated nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 10 that encode the protein comprising the amino acid sequence of SEQ ID NO: 5. The instant specification discloses that the polypeptides comprising the amino acid sequence presented in SEQ ID NO: 5 is a protein that shares structural and sequence similarity with leukocyte and blood associated proteins (LBAP).

Pages 27-52 of the instant application describes the uses and methods of the invention, and state that the nucleic acid molecules and proteins can be used in methods such as screening, detecting assays (labeled hybridization, PCR probes for detecting sequences and predicative medicine), production of expression vectors, manufacture of medicament for the treatment of a variety of diseases, production of anti-bodies for diagnostic purposes. The specification also states that the leukocyte and

blood associated proteins of the invention have structural similarity with putative haemopoietic membrane proteins. The specification further asserts that the leukocyte and blood associated proteins and leukocyte and blood associated nucleotide sequences, can be used for screening for drugs (or high throughput screening of cDNA libraries) effective in the treatment of the symptomatic or phenotypic manifestations of perturbing the normal function of the immune system of the body and can be used directly to treat disease and disorders.

However these are not considered to be specific or substantial utilities for either the nucleic acid molecules or proteins. The methods such as recombinant production of protein, southern blotting, PCR, detection assays, antibody production, complementary sequence hybridization, EST production, microarray production and DNA probe production are considered to be general methods, and are not considered to be specific and substantial utilities.

It is asserted in the specification that the leukocyte and blood associated protein (LBAP) encoded by leukocyte and blood associated polynucleotide has structural similarity with putative haemopoietic membrane proteins. Kaline et al and Baird et al. (cited in IDS filed November 12, 2003) disclose polynucleotides that encode polypeptides that are putative haemopoietic membrane proteins. However, the polypeptide of the invention encoded by the isolated polynucleotide sequence disclosed, has not been shown to have primary structural similarity with polypeptides encoded by polynucleotides present in Baird et al. and Kanline et al. . Also, there is no disease or disorder correlated with the leukocyte and blood associated protein (LBAP)

encoded by the nucleic acid sequence of the invention. The use of unknown amino acids encoded by polynucleotides, to determine structural similarity with other amino acid sequences by itself does not constitute a specific and substantial utility. Based on structural similarity alone, the specification attempts to assert that the new cDNA clone encodes a putative haemopoietic membrane protein. However function prediction from structure or structure prediction from function is not a reliable measure of utility. leukocyte and blood associated protein (LBAP) encoded by novel leukocyte and blood associated polynucleotide does not appear to have structural similarity to haemopoitic membrane proteins, but even if they did demonstrate a level of structural homology, since the function of leukocyte and blood associated protein (LBAP) is not known it would not be conclusive to assume, solely based on structure homology, that they have the same function and would have the same utility. It is necessary to carry out further characterization of this protein to asses the patentable utility, of the polynucleotide.

The specification discloses that the leukocyte and blood associated nucleic acid can be used for hybridization probes for screening libraries and microarray-based analysis. However these are not considered to be specific and substantial utilities. The utilities described are general and would apply to any polynucleotide.

In Brenner v. Manson, 148 U.SP.Q 689 (Sup. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to posses anticancer activity was alleged to be useful because the compound produced thereby was potentially useful as anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are

"useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotides encoding novel human proteins which have undetermined function or biological significance. Thus no actual or specific activity is attributed to the proteins identified in the specification as novel human proteins or the polynucleotides encoding them.

In **claims 5-6** the claimed transformed cell with a recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide sequence disclosed by SEQ ID NO: 10, is not supported by well established utility: cells may be used for expressing nucleic acid sequences but this is not a specific utility, because the use of the cell is generally applicable to any expression vector, and therefore the utility is not particular to the sequence being claimed for the cell. Moreover, the sequence itself does not provide for specific utility, as the function of sequence disclosed has not been determined in any art of record or shown in the application. Therefore, no specific utility is found for the claimed subject matter.

With regard to substantial utility, the claimed cell line is not supported by a substantial utility because the specification states that the cells can be used to express polypeptides of interest (page 49, example IX). A starting material that can only be used to produce a final product does not have a substantial utility. In this case the DNA sequence used to produce the protein of interest does not have an asserted or identified

substantial utility. The proposed research strategies to characterize potential products, specifically in regards to biological activities, do not constitute a substantial utility or a "real world use".

Because the claimed invention is not supported by a specific and substantial asserted utility for the reasons above, credibility has not been asserted. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein such that another non-asserted utility would be well established for the cell line.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3-6, 10 and 11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Even if the specification were enabling of how to use the leukocyte and blood associated nucleic acid molecules and proteins, enablement would not be found to be commensurate in scope with the claims. As discussed in ***USC 101 and 112*** rejections above, the specification has not taught the skilled artisan how to use the nucleic acid molecule and polypeptide of SEQ ID NO: 10 and 5 that are disclosed in the instant specification. If one skilled in the art does not know how to use these nucleic acid

molecules, the skilled artisan would clearly not know how to use the nucleic acid molecules encoding polypeptides that have structural similarity with haemopoietic membrane bound proteins.

Claims 3-6, 10 and 11 are rejected under 35 U.S.C 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims as presented encompass genomic DNA. The leukocyte and blood associated Protein clone was obtained from a cDNA library. The structure and sequence of the chromosomal DNA is not disclosed in the sufficient detail, so that one skilled in the art can reasonably conclude that the inventors had possession of the claimed invention. The person skilled in the art would not recognize in the current disclosure a description of the invention defined by the claim as it relates to genomic DNA for several reasons. Genes are extremely complex structures made of exons (presented in cDNAs corresponding to the genomic DNA) and introns (non-coding regions between the exons). The prior art does not teach genomic DNA corresponding to the disclosed cDNA or a family of proteins to which the current claimed encoded protein belongs for which there is a known conservation of encoding genomic structure. There are no general rules for predicting the number of exons and introns the genomic DNA would expect to have. The prediction is even more complicated due to the possibility of splice variants, so that the disclosed cDNA may not disclose all exons within the corresponding DNA because the alternative exons are particular to individual splice variants. Even acknowledging high

skill in molecular biology art, prediction of even the general structure of the claimed polynucleotide (*i.e.* number and general size of exons and introns), let alone the sequence of the polynucleotide, is not possible based on the information provided in the specification. There are no examples of genomic DNA disclosed. The coding sequences disclosed do not contain any introns sequence(s) since the sequences are cDNA, which is made of only exon sequences. It is not apparent that the claimed polynucleotide encompassing genomic DNA was obtained when the application was filed, nor was there any written description of such. For these reasons, it does not appear that applicants were in possession of the claimed invention as it pertains to genomic DNA at the time the application was filed. Because the specification merely discloses cDNA sequences, and does not describe the corresponding genomic DNAs, the written description requirement has not been met with respect to genomic DNA.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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